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November 13, 1981

Document Control Officer (TS-793)
Office of Toxic Substances
ENVIRONMENTAL PROTECTION AGENCY
Room E 401
401 "M" Street, Southwest
Washington, DC 20460

Dear Sir:

Re Docket Number OPTS-62013 and 62014

Monsanto Company is a broad-based manufacturer of industrial chemicals. Previously, Monsanto Company was the major producer of polychlorinated biphenyls in the U.S. As in the past, Monsanto Company continues to evaluate and monitor the potential health and environmental effects of chemical products produced by the company to ensure that our workers, customers and the general populace are not inadvertently exposed to agents that might pose a significant risk if improperly handled and used.

Monsanto Company offers the following comments on the proposed rule:

I. Appropriateness of the Suggested Regulatory Approach

Section 6(e) of the Toxic Substances Control Act, 15 U.S.C. 2605(e), was directed toward commercial production of polychlorinated biphenyls (PCB's) and was not intended by Congress at the outset to apply to traces of material incidentally produced as the result of a manufacturing process dedicated to production of specific non-PCB materials. The legislative history clearly refers to PCB's intended for commercial purposes and, in many instances, refers to them by trade name.

Consequently, any regulations developed under Section 6(e) should only deal with intentionally produced polychlorinated biphenyls. It is known, for example, that treatment of certain industrial wastes in a secondary treatment plant can result in production of trace levels

of PCB's in the course of neutralization, detoxification and destruction of other hazardous wastes. Certainly Congress had no knowledge of such incidental generation nor was there any Congressional intent to regulate such sources of incidental PCB generation.

Regulation of PCB's as a special case by Section 6(e) is totally unwarranted and unnecessary in view of other provisions of the law available for control of hazardous chemicals, particularly Section 6(a), etc. If the Administrator, after careful evaluation of the scientific evidence, finds that there is a basis for regulation of any chemical substance, including PCB's, by determination that it presents an unreasonable risk of injury to health or the environment, it may be regulated under these general sections.

II. The Nature of Human and Environmental Exposure -- Health and Environmental Effects of PCB's

Recent thorough reviews of the health and toxicity effects of PCB's, with particular emphasis on data obtained and published since 1975 when the Toxic Substances Control Act was being drafted, have been conducted by several independent reviewers, including the scientific staff of the Department of Medicine and Environmental Health of Monsanto Company. Results of these reviews have been published and will be submitted to the Agency in response to the mandate of the DC Circuit Court in EDF vs. EPA.

Results of these reviews, including an extensive scientific review of more than two dozen health studies dealing with human exposures to PCB's, fail to show a link between the chemical and human cancer (see attachment). The human epidemiology studies have shown that while exposure to PCB's can cause temporary skin problems, there are no clinically observable long-term health effects, including the occurrence of cancer.

All of the occupational studies of health effects agree that there has been no clinical illness associated with PCB exposure other than dermatitis (skin disorder). Studies of non-occupationally exposed populations have found neither dermatitis nor other clinical evidence of exposure-related effects.

These conclusions are based on an extensive review of published and unpublished epidemiologic studies which have been performed by a number of scientists in the United States and abroad, including those from Federal and State governmental agencies, universities and medical schools.

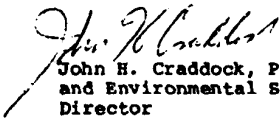
In addition, thorough reviews of the scientific and technical literature, relating to health effects of test animals exposed to PCB's, by several independent bodies show that PCB's are not "deadly toxins" as occasionally misrepresented in the news media. On the contrary, as pointed out in the attached summary report, any impact of PCB's on the environment is so slight as to be totally insignificant.

The report of National Research Council of the National Academy of Sciences ("Polychlorinated Biphenyls", National Academy of Sciences, Washington, DC, 1979) sums up even the most recent reviews:

"Although PCB's have been detected in the U.S. population, there have been no documented cases of PCB intoxication of humans other than those related to industrial exposure. Effects, when detectable, have been subtle rather than overt." (Page 122)

The Agency and the Administrator should re-evaluate and change their previous determination that any human exposure to PCB's is a significant exposure and presents an unreasonable risk in light of the recent data developed since the drafting of the 1976 Toxic Substances Control Act (after 1975). Regulations should be modified to reflect present scientific thinking and realistic rules developed that are less burdensome, over-protective and costly. Cost-effective rules should be proposed which take into account the relatively small risk associated with PCB exposure as compared to the enormous cost of unreasonable regulation.

Sincerely,



John H. Craddock, Product
and Environmental Safety
Director

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attachment

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